REMARKS

Present Status of the Application

Claims 32-36, 38-41, 45-48, 58-60 and 71 remain pending, along with elected species a) linseed oil for claims 32-36 and 38, b) palmitic acid for claims 40-41 and c) paclitaxel for claims 45-48.

Claims 32-36, 38-39 and 45-47, 58-60 and 71 were rejected under 35 USC 102(b) as being anticipated by Allen-Petit et al. (WO 2003/039612A1), as evidenced by Russel (Tung & Linseed oils, articles published on internet). Claim 48 was rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Russel. Claims 40-41 were rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Russel in view of Kashiwagi et al. (USP 5,336,698).

After considering the following discussions, a notice of allowance is respectfully solicited.

Discussions of 102 and 103 rejections

Claims 32-36, 38-39 and 45-47, 58-60 and 71 were rejected under 35 USC 102(b) as being anticipated by Allen-Petit et al. (WO 2003/039612A1), as evidenced by Russel (Tung & Linseed oils, articles published on internet). Claim 48 was rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Russel. Claims 40-41 were rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Russel in view of Kashiwagi et al. (USP 5,336,698).

At first, the Office Action relied on Russel as an evidence reference.

However, the reference Russell is an article published in the internet, which lacks of clear prior publication date or recognized credibility for its whole content. In this case, it is a doubtful reference, without either credibility or affirmed public assessable date.

Therefore, the Office Action should not cite this unreliable article as the evidence reference.

As admitted by the Office Action, Allen-Petit et al. fails to teach that linseed oil polymerizes. The Office Action relied on Russel for evidencing "the drying of the linseed oil is a result of polymerization by the action of atmospheric oxygen (autoxidation)".

Russel describes the differences between tung oil and linseed oil towards wood preservation. In addition the drying of oil films is described as a three step process the induction of which is characterized by oxidation of the oils and factors such as temperature, light and heavy metals/inhibitors in the oil, affect the oxidation (page 1, last paragraph). Thus according to Russel the polymerization of oils requires oxygen, the oxidation of the oils, a special temperature, light or heavy metals.

However, the conditions used to coat an implant in Allen-Petit et al. are the followings:

- use of fats or oils with reduced amount of multiple bonds,

- contact of the fats and oils to be used for coating with anti-oxidative and/or deoxidative compounds,

- short term contact to aerial oxygen at room temperature,

- light protection of the obtained coated implant.

Regarding multiple bonds

Oils require multiple bonds in order to polymerize and polymerization is faster the more multiple bonds are contained in an oil molecule or if several multiple bonds are conjugated within an oil molecule. This fact is also disclosed by Russel at page 1, paragraph 6. In contrast, Allen-Petit et al. reduces the amount of multiple bonds within the oil molecules by hydrogenation. Clearly, Allen-Petit et al. also reduces the ability of the oil molecules to polymerize.

Regarding anti-oxidative and/or deoxidative compounds

Russel points out that the polymerization of oils requires oxygen and that the polymerization process is induced by the oxidation of the oils. On the contrary, Allen-Petit et al. inhibits the oxidation of the oils, by using anti-oxidative and/or deoxidative compounds.

In Allen-Petit et al., for instance, alpha-tocopherol (see page 4, lines 25-26) is added to the coating mixture of oils and fats, because its anti-oxidant effect is believed to be the basis for the biocompatible properties of unsaturated oils and fats. Anti-oxidants have a higher tendency to oxidize and thereby protect other substances, e. g. fats or oils, against being oxidized and polymerized. So the alpha-tocopherol protects the fats or oils in the coating against oxidation.

As the polymerization of fats and oils relies on oxidation, it is clear that the polymerization of fats and oils is inhibited.

Furthermore, each implant of Allen-Petit et al. is dipped in a deoxidative solution (see step b, in page 9, line 20 of Allen-Petit et al.) before coating it with fats or oils. Deoxidation means the act or process of reducing from the state of an oxide. So the deoxidative molecules adhering to the surface of the implant reduce oxidized members of the fat or oil coating. Thus the deoxidative coating prevents also oxidation of fats and oils and in this way inhibits their polymerization, too.

In summary Allen-Petit et al. teaches to inhibit the oxidation of the oils and thus inhibit the polymerization of the oils.

Light protection

Russel states that light affects the induction of the oxidation of oils, i.e. the polymerization of oils. According to the present application, light is suited to enhance the polymerization of oils (see page 5, lines 14 to 17 of the present application).

Contrarily, Allen-Petit et al. advises to protect the freshly coated implant from light (page 10, lines 28-30). Allen-Petit et al. recommends conditions for the freshly coated implants that do not facilitate polymerization of oils and thus inhibits the polymerization of the oils.

Drying the oils

In Russel's contexts, "drying" of oils actually means polymerization of oils (page 1, paragraphs 1 and 2).

While in Allen-Petit et al., it is clearly stated that the freshly coated stents were air-dried to

let evaporate the solvent, e.g. ethanol (in step g and at page 20, lines 15-17 of Allen-Petit et al.). Thus in Allen-Petit et al., the terms "dried", "airdried" or "drying" merely means evaporating a solvent and not polymerizing oils.

In summary, neither Allen-Petit et al. alone nor Allen-Petit et al. evidenced by Russel disclose a medical product with a layer of polymerized or auto-polymerized substances like drying oils or linseed oil, of the present application. In contrast, the conditions for polymerization of oils or fats described by Russel clearly prove that the coating of medical surfaces with oils or fats disclosed by Allen-Petit et al. does not include polymerization or auto-polymerization of the fats or oils. Hence, the medical product of the present application is novel over Allen-Petit et al. alone as well as over Allen-Petit et al. evidenced by Russel.

In fact, as evidenced by Russel, Allen-Petit et al. teaches away from the present application. In Allen-Petit et al, the features of using fats or oils for coating with only minimal content of multiple bonds and introducing deoxidative and anti-oxidative compounds in the coating composition of Allen-Petit et al. would lead someone skilled in the art to non-polymerized oil coatings and thus to the opposite direction as compared to the present invention.

For claim 48, because of the above outlined reasons the present application is regarded as being inventive over Allen-Petit et al. even if evidenced by Russel.

On the other hand, the medical product of the present application is inventive and distinct from the prior products based on the following facts.

- The polymerization or auto-polymerization of oils on the surface of a medical product

generates a coating of the medical product with exceptionally good properties that are superior to the coatings described by Allen-Petit et al., Russel or Kashiwagi et al.. These properties of the obtained coating are, for example, being uniform, thin, stable, flexible and hemocompatible.

A uniform hemocompatible coating of a medical product is important because it means that the coating does not exhibit any gaps. Gaps would be of disadvantage because they present the unmodified surface of the medical product which could induce negative reactions by the body when implanted. In this context the stability and flexibility of the coating is also important. The coating of polymerized or auto-polymerized oils of the present application does neither break nor detach from the surface of the medical product by sterilization, implanting, expanding or because of blood contact.

In contrast, the coating layers of Allen-Petit et al. do not present a special uniformity or stability because they do not consist of a polymeric network. Instead they consist of adhered single molecules of oils or fats which adhere to the surface of a medical product only by hydrophobic interactions with the surface and one another and because of the nearly solid consistency. This becomes clear from the fact that Allen-Petit et al. discuss problems with stable adhering of the oil or fat coating to the surface of the medical product (see page 8, lines 15 - 19 of Allen-Petit et al.).

The property of a thin coating of a medical product is also of importance, since it optimizes the alteration of the outer and inner diameter of the medical product caused by the coating layers. The increase of the outer diameter should be kept as small as possible in order minimize overexpansion of the treated vessel by implanting the coated medical product. In addition, the

inner diameter should be kept as wide as possible in order to maximize the flow-through volume of blood through the inner diameter of the medical product.

Concerning the excellent hemocompatible properties of the coating of polymerized or auto-polymerized oils of the present application please refer to our remarks filed in response to the previous Office Action.

- In addition the auto-polymerization of oils on the surface of a medical product does not require any special catalysts because the auto-polymerization is catalyzed by atmospheric oxygen. This is especially of advantage since catalysts are foreign substances for the human body. When these foreign substances are introduced into the human body by implanting the medical product the reaction of the human body is not foreseeable. The foreign substances might also induce negative reactions by the body which could contribute to development of thrombosis or restenosis. Thus, using catalysts for polymerizing oils on surfaces, as described by Russel, is of no value for coating surfaces of medical products by polymerization or auto-polymerization of oils.

- Furthermore the polymerization or auto-polymerization of oils on the surface of a medical product forms a stable and uniform coating suitable as carrier for pharmaceutically active agents. In order to integrate active agents into the polymer layer on the one hand the active agents can be mixed with the oils and deposited onto surface of the medical product. During polymerization or auto-polymerization the active agents are incorporated into the emerging polymer network. This kind of incorporating is easy to perform and yields good release kinetics for the active agents. On the other hand, the active agents can be incorporated into the polymeric coating of the medical

product after completion of polymerization or auto-polymerization. This is done by a process of swelling the coating of medical product within a solution of the active agent. This process is possible because the completed polymeric coating is not dissolvable in aqueous or organic solvents. The coating of Allen-Petit et al. or Kashiwagi et al. would dissolve away when placed in a solvent because it does not consist of a polymeric network completely covering the whole medical product. Moreover, it is possible to incorporate as well active agents dissolvable in organic solvents as active agents which are solvable in aqueous solvents into the coating layer of the medical product and extend the spectrum of suited active agents. In addition, incorporating active agents after completion of the polymeric coating minimizes interactions of the active agents with the polymeric coating. Therefore adjusting the dosage, efficiency and release rates of the active agents are facilitated.

Clearly, the medical product of the present application distinguishes over the prior art product.

Russel describes using tung oil or linseed oil towards wood preservation. Thus Russel does neither disclose nor suggest a coating of a medical product with drying oils or linseed oil.

But. Kashiwagi et al. even does not describe a coating of a medical product via polymerized or auto-polymerized substances like drying oils or linseed oil. The polymers used by Kashiwagi are polymerized prior to applying it to the surface of the medical product. Thus, Kashiwagi fails to remedy the deficiencies as discussed above.

Even a combination of the teachings of Allen-Petit et al., Russel and Kashiwagi et al. does not disclose nor suggest coat a medical product with polymerized or auto-polymerized substances

like drying oils or linseed oil after depositing the oils to the surface of the medical product and by means of exposure to aerial oxygen and UV light. Therefore the present invention as represented by the claims is also regarded as being inventive over these references.

According, reconsideration and withdrawn of these 102 and 103 rejections are respectfully requested.

CONCLUSION

For at least the foregoing reasons, it is believed that all the pending claims of the present application patently define over the prior art and are in proper condition for allowance. If the Examiner believes that a telephone conference would expedite the examination of the above-identified patent application, the Examiner is invited to call the undersigned.

Respectfully submitted,
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